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PATENT
540591-705-1
JUL 28 2003
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7-3-03

SIN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Jose Gutierrez-Rocca et al.
Serial No. : 10/086,059
For : **A SUSTAINED RELEASE
PHARMACEUTICAL FORMULATION**
Filed : February 27, 2002
Group Art Unit : 1617
Examiner : Theodore J. Criares

745 Fifth Avenue
New York, NY 10151

I hereby certify that this correspondence is being deposited with
the United States Postal Service as first class mail in an envelope
addressed to: Mail Stop AF Commissioner for Patents, P.O.
Box 1450, Alexandria, VA 22313-1450, on July 23, 2003.

Jerome Rosenstock, Reg. No. 25,456

Name of Applicant, Assignee or Registered Representative

Signature

July 23, 2003

Date of Signature

RESPONSE UNDER 37 CFR § 1.111

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA. 22313-1450

Sir:

This is in response to the Office Acton mailed on June 30, 2003.

Claims 1 through 16 are presently in the subject application.

Enclosed is a copy of the subject application as filed ("COPY"). The undersigned, Jerome Rosenstock, herein certifies that the COPY is a true copy of the subject application as filed. Accordingly there was an original claim 10. Restriction has been required under 35 U.S.C. § 121, as follows,

GROUP I Drawn to compositions to prolonged release formulations, comprising original claims 1 through 8, and 11-12 of the COPY; and

GROUP II Drawn to processes for the preparation of sustained/prolonged release formulations, comprising original claims 9-10 and 13-16 of the COPY.

In view of the mandatory requirements of 35 U.S.C. § 121, Applicant provisionally elects **GROUP I**, comprising original claims 1-8 and 11-12 of the COPY, with traverse.

Favorable reconsideration and withdrawal of the requirement for restriction, particularly the restriction among GROUPS I and II, is requested. It is believed that a proper search to determine the patentability of the compositions of prolonged release formulations of claims 1-8 and 11-12 of the COPY would include the process for the preparation of these formulations, as defined in claims 9-10 and 13-16.

The Examiner's requirement for restriction was made pursuant to the provisions of the MPEP § 806.05(e). Applicant kindly refers the Examiner to a provision of the MPEP § 803, which provides that:

If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

In the present case it is courteously submitted that an examination of the entire application and all of the claims can be made without serious burden. The Examiner will have to study Applicant's entire specification in connection with his examination of the elected invention. No additional effort will be required to study the specification with respect to the remaining claims.

Accordingly, withdrawal of the restriction requirement is respectfully requested.

The Examiner is hereby authorized to call the undersigned attorney of record "collect" on any matter connected with this application. The telephone number is 212-588-0800. In the absence of the undersigned attorney of record, the call will be accepted by any attorney empowered in this application.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP

By: 

Jerome Rosenstock
Attorney for Applicants
Registration No. 25,456
(212) 588-0800

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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	540591-7095.1
First Inventor	Jose Gutierrez-Rocca
Title	A SUSTAINED RELEASE PHARMACEUTICAL FORMULATION
Express Mail Label No.	EL 819167707 US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO: Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231

1. ☒ Fee Transmittal Form (e.g., PTO/SB/17)
(Submit an original, and a duplicate for fee processing)
2. ☐ Applicant claims small entity status.
See 37 CFR 1.27.
3. ☒ Specification [Total Pages 18]
(preferred arrangement set forth below)
 - Descriptive title of the invention
 - Cross References to Related Applications
 - Statement Regarding Fed sponsored R & D
 - Reference to sequence listing, a table, or a computer program listing appendix.
 - Background of the Invention
 - Brief Summary of the Invention
 - Brief Description of the Drawings (if filed)
 - Detailed Description
 - Claim(s)
 - Abstract of the Disclosure
4. ☐ Drawing(s) (35 U.S.C. 113) [Total Sheets ____]
5. Oath or Declaration [Total Pages ____]
 - a. ☐ Newly executed (original or copy)
 - b. ☐ Copy from a prior application (37 CFR 1.63(d))
(for continuation/divisional with Box 18 completed)
 - i. ☐ **DELETION OF INVENTOR(S)**
Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. ☐ Application Data Sheet. See 37 CFR 1.76.

7. ☐ CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix)
8. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)
 - a. ☐ Computer Readable Form (CFR)
 - b. Specification sequence Listing on:
 - i. ☐ CD-ROM or CD-R (2 copies); or
 - ii. ☐ paper
 - c. ☐ Statements verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

9. ☐ Assignment Papers (cover sheet & documents(s))
10. ☐ 37 CFR 3.73(b) Statement
☐ Power of Attorney
(when there is an assignee)
11. ☐ English Translation Document (if applicable)
12. ☐ Information Disclosure Statement (IDS)/PTO-1449 ☐ Copies of IDS Citations
13. ☐ Preliminary Amendment
14. ☒ Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
15. ☐ Certified Copy of Priority Document(s)
(if foreign priority is claimed)
16. ☐ Request and Certification under 35 U.S.C. 122(b)(2)(B)(i).
Applicant must attach from PTO/SB/35 or its equivalent.
17. ☐ Other:

18. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment, or in an Application Data Sheet under 37 CFR 1.76:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: ____/
Prior application information: Examiner: ____ Group/Art Unit:

For CONTINUATION OR DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

19. CORRESPONDENCE ADDRESS

☒ Customer Number or Bar Code Label (Insert Customer No. or Attach Bar code label here) or ☐ Correspondence address below

Name

Name (Print/Type)	JEROME ROSENSTOCK, ESQ.	Registration No. (Attorney/Agent)	25,456
Signature	<i>Jerome Rosenstock</i>	Date	February 27, 2002

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FEE TRANSMITTAL
for FY 2001

Patent fees are subject to annual revision.

Complete if Known

Application Number	
Filing Date	
First Named Inventor	Jose Gutierrez-Rocca
Examiner Name	
Group/Art Unit	
Attorney Docket No.	540591-7095-1

TOTAL AMOUNT OF PAYMENT

(\$992.00)

METHOD OF PAYMENT1. ☒

The Commissioner is hereby authorized to charge indicated fees and credit any over payments to:

Frommer Lawrence & Haug LLP

50-0320

Deposit
Account
Name

Deposit
Account
Number☒ Charge any Additional Fee Required
Under 37 CFR 1.16 and 1.17☐ Charge the Issue Fee Set in 37 CFR
1.18 at the Mailing of the Notice of
Allowance2. ☐ Payment Enclosed☒ Check☐ Money Order☐ Other**FEE CALCULATION****1. BASIC FILING FEE**

Large Fee Code	Entity Fee (\$)	Small Fee Code	Entity Fee (\$)	Fee Description	Fee Paid
101	740	201	370	Utility filing fee	740.00
106	330	206	165	Design filing fee	
107	510	207	255	Plant filing fee	
108	740	208	370	Reissue filing fee	
114	160	214	80	Provisional filing fee	
SUBTOTAL (1)					740.00

2. EXTRA CLAIM FEES

Total Claims	Extra Claim	Fee from below	Fee Paid
16	-20** = 0	18	0.00
Ind. Claims	-3** = 3	84	252.00
Multiple Dependent			

** or number previously paid, if greater; for reissues, see below

Large Fee Code	Entity Fee (\$)	Small Fee Code	Entity Fee (\$)	Fee Description
103	18	203	9	Claims in excess of 20
102	84	202	42	Independent claims in excess of 3
104	280	204	140	Multiple dependent claim, if not paid
109	84	209	42	** Reissue independent claims over original patent
110	18	210	9	** Reissue claims in excess of 20 and over original patent
107	510	207	255	Plant filing fee
SUBTOTAL (2) (\$252.00)				

FEE CALCULATION**3- ADDITIONAL FEES**

Large Fee Code	Entity Fee (\$)	Small Fee Code	Entity Fee (\$)	Fee Description	Fee Paid
105	130	205	65	Surcharge - late filing fee or oath	
127	50	227	25	Surcharge - late provisional filing fee or Cover sheet	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request of reexamination	
112	920*	112	920*	Requesting publication of SIR prior to Examiner action	
113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for reply within first month	
116	400	216	200	Extension for reply within second month	
117	920	217	460	Extension for reply within third month	
118	1,440	218	720	Extension for reply within fourth month	
128	1,960	228	980	Extension for reply within fifth month	
119	320	219	160	Notice of Appeal	
120	320	220	160	Filing a brief in support of an appeal	
121	280	221	140	Request for oral hearing	
138	1,510	138	1,510	Petition to institute a public use Proceeding	
140	110	240	55	Petition to revive - unavoidable	
141	1,280	241	640	Petition to revive- unintentional	
142	1,280	242	640	Utility issue fee (or reissue)	
143	460	243	230	Design issue fee	
144	620	244	310	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Petitions related to provisional Applications	
126	180	126	180	Submission of Information Disclosure Statement	
581	40	581	40	Recording each patent assignment per property (times number of properties)	
146	740	246	370	Filing a submission after final rejection (37 CFR 1.129(a))	
149	740	249	370	For each additional invention to be examined (37 CFR 1.129(b))	
Other fee (specify)					
Other fee (specify)					
SUBTOTAL (3) (\$0.00)					

* Reduced by Basic Filing Fee

SUBMITTED BY

Typed or Printed Name

JEROME ROSENSTOCK

Signature



Date

2/27/02

Complete (if applicable)

Reg. Number

25,456

Deposit Account

50-0320

WARNING: Information on this form may become public. credit card information should not be included on this form.**Provide credit card information and authorization on PTO-2038.**

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

00053554

File

CERTIFICATE OF MAILING – SEPARATE PAPER

Attorney Docket No. : 540591-7095.1
Serial No. : Not Yet Known
Filed : Herewith
Applicant(s) : Jose Gutierrez-Rocca

Date of Deposit 02/ 27/02 via "Express Mail" # EL 819167707 US

I hereby certify that a Provisional Patent Application and related documents for the above-referenced application are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to:

Assistant Commissioner for Patents
Washington, D.C. 20231

Charles Jackson

(Typed or printed name of person mailing paper or fee)

Charles Jackson

(Signature of person mailing paper or fee)